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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,921	12/22/2000	Kevin E. Dwyer	2265-15	2764

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/964,415

Applicant(s)
Badejo, I.

Examiner
Patricia Patten

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1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136. a. In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. 35 U.S.C. § 133.
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704.b.

Status

- 1) ☒ Responsive to communication(s) filed on Nov 25, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) 9 and 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1. Notice of References Cited (PTO-892) | 4. Interview Summary (PTO 413) Paper No's |
| 2. Notice of Draftsperson's Patent Drawing Review (PTO 948) | 5. Notice of Informal Patent Application (PTO 152) |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No's <u>10 + 13</u> | 6. Other |

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DETAILED ACTION

Claims 1-29 are pending in the application. Claims 9 and 11-23 were withdrawn from further consideration on the merits as being drawn to a non-elected invention in Paper No. 7.

Claims 1-8, 10, and 24-29 have been presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement filed 9/6/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

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Claims 1- 8 and 10 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office Action.

Applicants arguments were considered, but not found convincing. There is no teaching within the Instant specification whereby the ordinary artisan could determine what Applicants mean by 'acidic buffering potential' or the degree of 'potential' that Applicants are referring to. Claims are read in light of the specification. In the Instant case, there is no definition for the term 'acidic buffering potential' or any data which would represent different compositions which produce specific pH's in solution. Although the claims are deemed indefinite because said phrase is not clearly delineated, the Examiner still examined the claims as though the composition offers at least some hydrogen ions to the surrounding environment (as in the previous Office Action).

Claims 1- 8 and 10 remain rejected, and claims 24-29 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 24-29 are drawn to a composition comprising a bone growth protein, a substrate, a source of calcium and a source of phosphate and a composition comprising a bone

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growth protein and an acidic calcium phosphate respectively. Claims 24-29 all recite wherein the pH of a solution is lowered to a specific range upon placing said composition in the solution.

Applicants' arguments were fully considered, but were not found persuasive.

Applicants argue that "Where Applicants invention departs from the prior art is not its use of acidic buffer salts *per se*, but in providing such salts so as to ensure an acidic pH environment to enhance the activity of the bone growth factor" (p.4, Arguments). Applicants further point out that "Enablement is particularly clear in light of the literally dozens, if not hundreds, of experiments on laboratory rats represented by the data in Figures 2-10".

It is not found in the data presented in Figures 2-8 wherein any 'acidic buffering potential' or the potential of any of the compositions to lower the pH level of a solution to between about 4 and 7 (or any of the specific ranges as recited in claims 24-29) has been displayed. As discussed in the previous Office Action, the state of the art is unpredictable. Applicants are stating that their invention performs a specific function of lowering pH, or acting as an acidic buffer, but no evidence of such has been disclosed. There has been no evidence displayed which would indicate any change of pH in

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solution after the composition has been introduced. Thus, it is deemed that a composition comprising an acidic calcium phosphate salt may buffer the immediate surroundings of the composition, however Applicants are *claiming* that the composition will buffer any solution, or lower the pH to a specific range in any solution.

Claim Rejections - 35 USC § 102

Claims 1-5, 8 and 10 remain rejected and claims 24-27 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Ohura et al (1999). Claims 24-27 are new claims drawn to the same composition as described in claims 1-5 and 8, but have language which states 'wherein the pH of a solution initially having a physiological pH is lowered...[to several pH ranges]'.

Applicants' arguments were fully considered but not found persuasive.

Applicants first argue that there is no teaching in Ohura of a composition having an acidic buffering potential (p.6, Arguments). It is noted that the claims are composition claims:

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"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are **produced by identical or substantially identical processes**, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Applicant previously argued that "Where Applicants invention departs from the prior art is not its use of acidic buffer salts *per se*, but in providing such salts so as to ensure an acidic pH environment to enhance the activity of the bone growth factor" (p.4, Arguments). It is deemed that because Ohara et al. taught that the composition contained the same ingredients (i.e., monocalcium phosphate monohydrate being one component), that the 'buffering potential' must have been an inherent property of the composition.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 remain rejected and new claims 28-29 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Kwan et al. (US 6,187,047 B1) in view of Constantz (US 5,047,031). Claims 28-29 are specifically drawn to a composition comprising a bone growth protein selected from the TGF- β superfamily, an acidic calcium phosphate salt comprising calcium monophosphate for example, wherein the pH of a solution is lowered when the composition is placed in the solution.

Applicants' arguments were fully considered, but not found persuasive.

Applicants argue that 'In terms of the present specification...these compounds have, in the formula $x\text{CaO} \cdot \text{P}_2\text{O}_5$ ' (p.7-Arguments). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., specific formulas) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Applicants further state that they 'do not claim all compositions comprising an acidic calcium phosphate salt, but only those having an acidic buffering capacity or the capability of providing an acidic pH to a solution' (p.7-Arguments). As stated in the rejection under 35 U.S.C. 112 Second paragraph (*supra*), the Examiner has interpreted the claims to mean that the composition has the tendency to donate a proton in solution. Because Constanz disclosed acidic calcium such as brushite (calcium monophosphate), the ordinary artisan would have recognized that the 'acidic' calcium had a tendency to donate a proton in solution.

Please note that the specific species of 'TGF- β ' and 'calcium monophosphate' as recited in claims 28 and 29 were disclosed by each reference separately as mentioned in the previous Office Action. Thus, these claims are obviated by the combination of the references.

Thus, the compositions were *prima facie* obvious to one of ordinary skill in the art at the time the Invention was filed. Applicants argue that the novelty of the Instant invention is the 'acidic buffering potential' of the composition. However, the claims, broadly recited, are anticipated and/or obvious in light of the prior art. As discussed previously, 'a composition is a composition' (In re Best). The Examiner cannot tell the difference between the composition being claimed and the prior art composition as in

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the rejection under 35 U.S.C 102(b). It appears that Applicants may be reciting a new discovery of an old composition, however, 1) the new discovery is unclear because the Specification does not clearly teach where any particular ranges of pH can be established by any of the compositions (Please see rejection under 35 U.S.C. 112 First and Second paragraphs supra) and 2) an inherent property of an old composition does not materially change the composition. Further, the addition of bone growth proteins to acidic forms of calcium phosphate was obvious in light of the references under the 35 U.S.C. 103(a) rejection because both of these substances were known in the art to be combined with bone implants.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

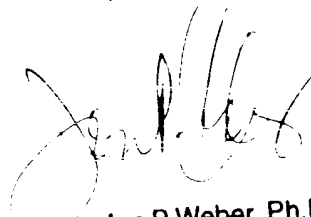
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner